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In re Application of
Wohlgemuth et al
Serial No. : 10/006,290
Filed : 22 October 2001
Attorney Ref No. : 506612000100

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on 12 October 2006, to review the restriction requirement. The delay in acting on this petition is regretted.

BACKGROUND

This application was filed under 35 USC 111(a) on 22 October 2001. On 23 September 2005, the examiner made an eight-way restriction requirement and requested that applicants elect a single sequence.

Applicants elected Group V and SEQ ID No 4758, with traverse.

On 13 February 2006, the examiner considered the traversal and made the restriction requirement FINAL. The elected claims 55, 60 and 66-72 were rejected under 35 USC 112, first and second paragraphs.

On 19 July 2006, the examiner rejected claims 55 and 66-72 under 35 USC 112, first paragraph as failing to comply with the enablement requirement.

On 23 January 2007, the examiner rejected claims 55, 66 and 68-72 under 35 USC 112, first paragraph as failing to comply with the enablement requirement. The action was made FINAL.

This petition was filed 12 October 2006.

DISCUSSION

The application, file history and petition under 37 C.F.R. 1.144, to request review of the restriction requirement has been considered. The petition argues that the sequences should be examined together in view of MPEP 803.02 or MPEP 803.04. These arguments will be addressed in turn.

A review of the file history shows that the application was filed with a 596 page specification and 1527 page sequence listing which lists 8832 sequences.

Applicants elected Group V, drawn to a method of diagnosing or monitoring transplant rejection in a patient comprising determining the RNA level transcribed from a DNA sequence. Claim 55 currently recites a list of sequences in the alternative, one of which is the elected sequence SEQ ID No 4758.

Claim 55 is reproduced below:

> Claim 55 (Currently amended): A method of diagnosing or monitoring transplant rejection in a patient, comprising determining the ~~expression level of a nucleic acid~~ RNA level transcribed from DNA in said patient to diagnose or monitor transplant rejection wherein said ~~nucleic acid~~ DNA comprises a ~~nucleic acid~~ DNA selected from the group consisting of SEQ ID NO: 3702, SEQ ID NO: 2073, SEQ ID NO: 213, SEQ ID NO: 3028, SEQ ID NO: 4758, SEQ ID NO: 6299, SEQ ID NO: 832, SEQ ID NO: 2143, SEQ ID NO: 3651, and SEQ ID NO: 3750.

MPEP 803.02, first paragraph, states:

> When the Markush group occurs in a claim reciting a process or a combination (not a single compound) it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship and it is clear from their very nature or from the prior art that all of them possess this property.

A review of Table 8 shows that the nucleic acids used in the method have non-homologous sequences arising from structurally and functionally different types of genes. For example:

SEQ ID NO 4758 is from a gene putatively encoding a natural killer cell receptor

GGGCAGAGAAGGTGGAGAGTAAAGA
CCCAACATTACTAACAATGATACAG

SEQ ID No 213 is from a gene putatively encoding an Activation mRNA

ATTTATATTAGTTTAGCCAAAGGATAA
GTGTCCTATGGGGATGGTCCACTGTC
ACTGTTTCTCTGCTGTT

SEQ ID No 2073 is from a gene putatively encoding an Adrenomedulin mRNA

TGAAAGAGAAAGACTGATTACCTCCT
GTGTGGAAGAAGGAAACACCGAGT

SEQ ID No 2143 is from a gene putatively encoding an Interleukin 1 receptor 8 beta chain

ACCAAGGCTAGAACCACCTGCCTATA
TTTTTTGTTAAATGATTTCATTCA

Given the diverse structural and functional differences of these sequences, it is not readily apparent from their very nature or from the prior art that the sequences used in this method possess a property in common which is mainly responsible for their function in the claimed relationship, i.e, as a means to monitor transplant rejection.

Even if MPEP 803.02 applied to this method claim, it is noted that the examiner is only required to extend the search and examination to a sequence species when the elected species is found allowable.

> "On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended...."

Because Claim 55 is currently rejected under 35 USC 112, first paragraph for lack of enablement, there would be no requirement for the examiner to extend the search to a second species.

The petition argues that under MPEP 803.02, the sequences should be searched together because it would not be burdensome. Burden is defined in MPEP 808.02, which states:

> (C) A different field of search : Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes /subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together....

Each sequence search would require a different search query, along with a review and analysis of the prior art cited in the search results. A search for SEQ ID NO 4758 would not likely identify

prior art reading upon SEQ ID NO 213 and vice versa. Moreover, the text search terms required for SEQ ID NO 4758 (natural killer cell receptor) and the text search terms required for SEQ ID No 213 (activation mRNA) are distinct: prior art obtained from one search would not be useful in examination of the second sequence. For these reasons, a search of ten sequences concurrently would be a serious burden on the Office.

The petition also argues that the ten sequences should be searched together in view of MPEP 803.04. Applicants reference to the U.S. Patent and Trademark Office policy regarding the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996) is acknowledged, however, not found persuasive on the basis that this policy regarding the partial waiving of the requirements of 37 CFR 1.141 is such that it will permit a reasonable number of nucleotide sequences to be claimed in a single application. Under the policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction. The waiver is permissive and not a requirement. The waiver pertains to specifically nucleotide product claims and not to process claims which use polynucleotide sequences. The present restriction requirement conforms with this policy as it has required that the application be limited to a single sequence. Applicants are reminded that one is within the range of up to ten and that a search and examination of ten sequences would be a serious burden on the Office.

DECISION

For these reasons, the petition under 37 C.F.R. 1.144 to request review of the restriction requirement and request rejoinder of the oligonucleotide sequences set forth in claim 55 is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Applicants remain under obligation to reply to the Final Office action mailed 23 January 2007 with in the response time specified therein or as extendable under 37 CFR 1.136(a).

Should there be any questions regarding this decision, please contact Quality Assurance Specialist/Program Manager Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

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